Rapid HIV and HCV Testing Guidance

for

Clearview® COMPLETE HIV 1/2

OraQuick® ADVANCE Rapid HIV 1/2

OraQuick® HCV Rapid Antibody Test

January 2014

Introduction

The purpose of this document is to provide guidance when using rapid testing technology. This guidance was designed for Utah Department of Health (UDOH) funded agencies, but may be used by any site that conducts rapid HIV or Hepatitis C (HCV) testing. UDOH funded agencies will receive a 30-day advance notice of any procedure changes, for everyone else using this guidance; we recommend to visit our provider resource page once a year.

Please direct questions or comments to the people listed below:

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Resources

Rapid testing guidance and other resources, such as required logs, are located on the Communicable Disease Prevention Program (CDPP) provider resource page. To access the webpage visit: http://health.utah.gov/cdc/hivprevention/hiv_prev_provider_resources.htm

Disclaimer

The Utah Department of Health does not endorse specific products or brands. The use of a brand/product name is for demonstration purposes only.

Table of Contents

1. General Information

1.1 Approved Test Devices

Throughout this document, the term 'rapid test' refers to the test devices listed below. As of the revision date listed on the title page, no other test devices are approved for use at publicly funded HIV and HCV test sites in the State of Utah. Test kits and external controls may be purchased directly from each manufacturer listed below:

Alere North America
51 Sawyer Road, Suite 200
Waltham, MA 02453-3448
(877) 441-7440
www.alere.com

Product name: **Clearview® COMPLETE HIV 1/2**
Product number: 92111
HIV Reactive / Nonreactive control number: 92112
Product website: http://www.alere.com/us/en/product-details/clearview-complete-hiv-1-2.html

OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015-1360
www.orasure.com
800/672-7873

Product name: **OraQuick® ADVANCE Rapid HIV 1/2 Antibody Test**
Product number: 1001-0078 (100 count)
Product number: 1001-0078 (25 count)
OraQuick® ADVANCE Rapid HIV-1/2 Control number: 1001-0077
Product website: http://www.orasure.com/products-infectious/products-infectious-oraquick.asp

Product name: **OraQuick® Rapid HCV Antibody Test**
Product number: 1001-0180 (100 count)
Product number: 1001-0181 (25 count)
OraQuick® ADVANCE Rapid HCV Control number: 1001-0182
Product website: http://www.orasure.com/products-infectious/products-infectious-oraquick-hcv.asp

1.2 Testing for HIV-2 in the United States

Below is an excerpt from the MMWR, July 17, 1992 / 41(RR12); 1-9, published by the Centers for Disease Control and Prevention. Please visit http://www.CDC.gov/mmwr/preview/mmwrhtml/00038078.htm to view the full document.

"Because epidemiologic data indicate that the prevalence of HIV-2 in the United States is extremely low, CDC does not recommend routine testing for HIV-2 at U.S. HIV counseling and test sites or in settings other than blood centers. However, when HIV testing is to be performed, tests for antibodies to both HIV-1 and HIV-2 should be obtained if demographic or behavioral information suggests that HIV-2 infection might be present".

2. General Start-up Requirements

Before any site may initiate rapid testing, the following items are to be completed and documentation provided to the Utah Department of Health.

☐ **Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver**

☐ **Documentation of Occupational Safety and Health Administration (OSHA) precautions for blood borne pathogens including:**

- Written exposure control plan
- Hepatitis B vaccination records or hepatitis B vaccination opt-out forms
- Training for all employees with occupational exposure
- Post-exposure evaluation/follow-up plan for all employees who have had an exposure incident

☐ **Biohazard Waste Disposal Plan that follows federal, state and local regulations including:**

- Sharps containers/biohazard disposal
- 10% bleach solution for biohazard spills

☐ **State of Utah Training and Certification**

- HIV, STD, Viral Hepatitis FACTS Class
- Lab Technician Training and Certification
- Fundamentals of HIV Prevention Counseling

2.1 CLIA Certificate of Waiver

The rapid HIV and HCV tests approved for use in the State of Utah are classified as "waived" under Federal regulations for the Clinical Laboratory Improvement Amendment of 1988.

Visit http://www.cms.hhs.gov/clia for a full listing of certification requirements.

Visit http://www.cms.hhs.gov/clia to apply for a certificate of waiver.

2.2 Blood Borne Pathogens

Individuals collecting blood specimens or who may encounter an occupational exposure to potential infectious materials must meet the U.S. Department of Labor Occupational Health and Safety Administration (OSHA) standards for blood borne pathogens. For more information visit: https://www.osha.gov/SLTC/bloodbornepathogens/index.html

2.3 Universal Precautions

Treat all human blood as if it is known to be infectious with HIV, Hepatitis B or C virus, and other blood borne pathogens. Sites must follow procedures for biohazard safety including:

- **ALWAYS** wear gloves when handling blood or body fluids
- Thoroughly wash hands with soap and water after any contact with blood or body fluids
- Prior to testing, discuss with a supervisor any cuts, abrasions or skin rashes on hands or lower arms that may allow for easier transmission of infection
- Dispose of gloves, absorbent work surfaces, and used testing materials in biohazard waste bags
- **AVOID** personal activities like eating, drinking, applying make-up and touching faces or eyes in a workspace where specimen collection and testing occur

2.4 Cleaning Up Biohazard Spills

- Wear protective equipment when cleaning a spill
- Clean up blood spills or body fluids immediately with absorbent towels
- Clean the area with a 10% bleach and water solution (1 part bleach, 9 parts water)
- Wipe up spill with absorbent towels
- Disinfect the area again with the 10% bleach solution and let air dry
- Throw away all contaminated materials in a biohazard waste container
- For more information on "laboratory spills" visit www.CDC.gov

2.5 Hepatitis B Vaccination Record or Opt-out Forms

All people who certify as lab technicians need to have documentation in their personnel or volunteer file of either hepatitis B vaccination or an opt-out form. Vaccination records can usually be obtained from private doctors, public clinics or state agencies, and opt-out forms can be created at an agency or retrieved online. It is important to note that even with proper lab set-up, any technician can come into contact with infectious bodily fluids. Hepatitis B vaccination protects against hepatitis B virus. Signing an opt-out form acknowledges that the individual chooses not to have the hepatitis B vaccination and accepts responsibility of possible infection of hepatitis B and future treatment.

2.6 Establishing Policies and Procedures

When establishing a site for rapid testing, program policies and procedures must address:

- Confidentiality
- Staff training and proficiency
- Quality assurance
- HIV and HCV counseling
- Record keeping
- Appropriate referrals and referral tracking to other HIV prevention services, Partner Services, HIV medical care and HCV diagnostic testing, treatment and other supportive services

Additional information to the above recommendations/documents, are available from UDOH CDPP. An agency may establish their own policies and procedures but their standards must meet UDOH guidelines.

3. Training

3.1 Lab Technician Training and Certification

All Utah Department of Health grantees wanting to certify as lab technicians need to attend a State of Utah-sponsored training course, complete a knowledge assessment and pass a supervised observation before testing clients and interpreting the results.

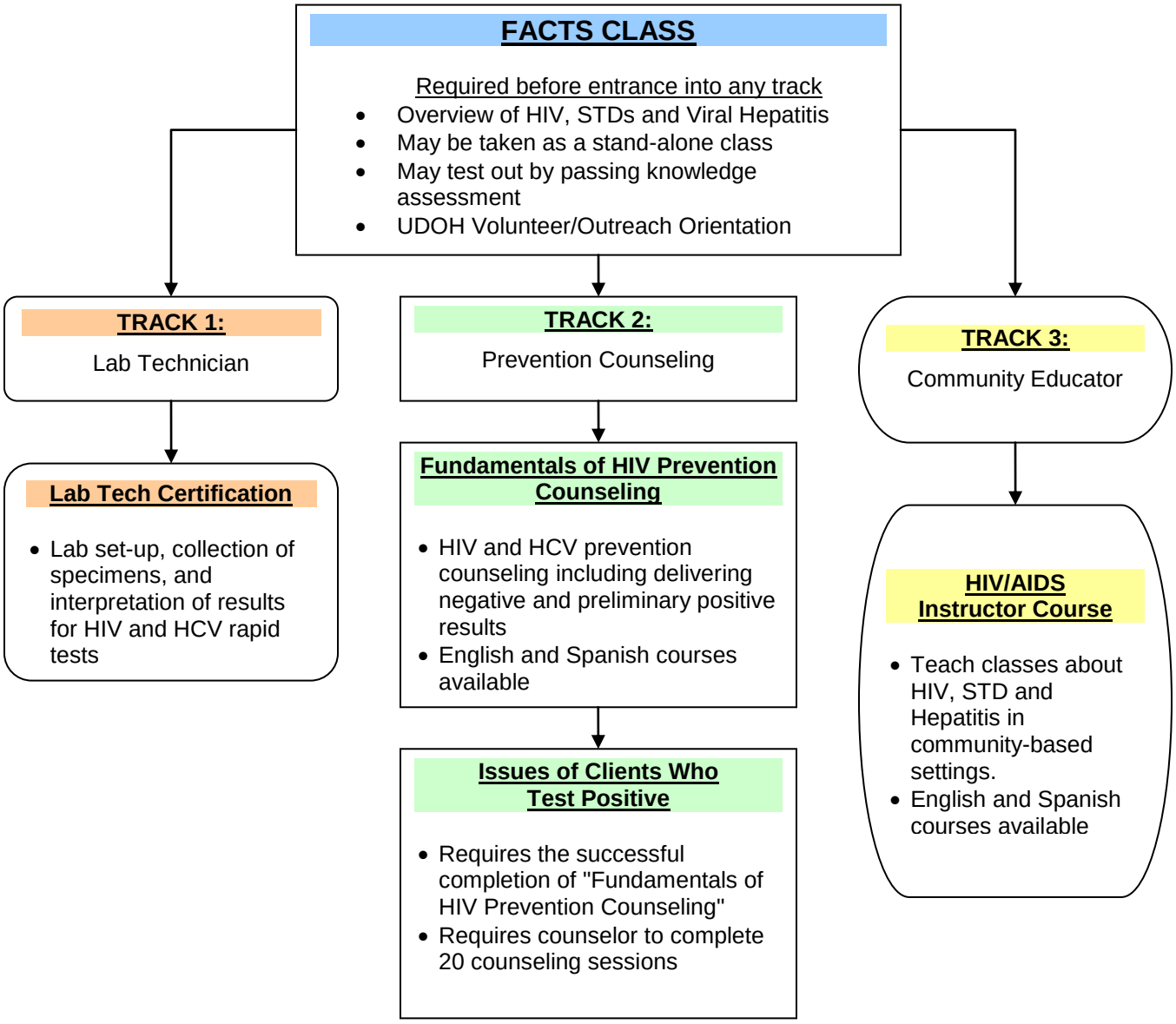
Prospective lab technicians must attend the FACTS training and the lab technician certification course. Prospective lab technicians are not required to attend the Fundamentals of HIV Prevention Counseling course or Issues of Clients who test Positive course, unless they will also provide counseling activities.

For more information on the training schedule please visit:
http://health.utah.gov/cdc/hiv_testing.htm#workshops

3.2 HIV and HCV Prevention Counselor Training

The contract between the Utah Department of Health and funded agencies mandates that all test site personnel who perform HIV/HCV counseling must attend and pass State of Utah-sponsored HIV/HCV prevention counselor training. Refer to specific contract for counselor training requirements.

Training Tracks



4. Control Kits and Test Kits

4.1 Control Kits

Each manufacturer produces test controls that validate the correct operation of a test device. The controls are unique to each test device and each manufacturer. The exchange of controls and test devices within or between manufacturers is not permitted and the result may not indicate whether the test device is operating within the manufacturer's specification. For example, OraQuick controls cannot be run on Clearview tests.

Control Kit Storage Temperature and Monitoring:
Refrigerate and maintain control kits at a consistent temperature. No warm-up is required before use.

Control Kit Type	Frequency	Temperature Range
Clearview® COMPLETE	Monitor every business day	35°- 46°F or 2°- 8°C
OraQuick® ADVANCE & HCV	Monitor every business day	35°- 46°F or 2°- 8°C

Control Kit Expiration:
If the controls are expired, dispose of them in a biohazard waste container. Similarly, if the fluid in the vials is cloudy or discolored, immediately discard them in a biohazard waste container and open a new box of controls.

Control Kit Type	Stable Period - Sealed	Stable Period - Open
Clearview® COMPLETE	Expiration date printed on vial	Expiration date printed on vial
OraQuick® ADVANCE &HCV	Expiration date printed on vial	Eight weeks after first use

4.1.1 Storage during Outreach Events

When conducting off-site/outreach testing it will be necessary to transport controls from the main facility to the off-site/outreach location. Best practice is to transport two sets of controls in a hard-sided, well-insulated, portable cooler that maintains a consistent temperature. Temperature should be monitored every 30 minutes. 'Blue Ice' or similar frozen packs should be used to help maintain temperature. If the temperature inside the cooler exceeds 35°- 46°F or 2°- 8°C, the controls must be discarded.

4.2 Test Kits

All rapid test kits require storage at different temperatures. Since most tests are usually stored in the same location, an average temperature range has been supplied that would ensure all tests are stored and maintained in the acceptable temperature range. If test kits are refrigerated, bring them to room temperature before use (approximately 30 minutes).

Test Kit Storage Temperature and Monitoring:

Test Kit Type	Frequency	Temperature Range
Clearview® COMPLETE	Monitor every business day	46°- 86°F or 8°-30°C
OraQuick® ADVANCE HIV	Monitor every business day	35°- 80°F or 2°-27°C
OraQuick® HCV	Monitor every business day	36°- 86°F or 2°-30°C

Average temperature range for all tests	**Monitor every business day**	**46°- 80°F or 8°-27°C**

Test Kit Expiration:

Test Kit Type	Expiration Date
Clearview® COMPLETE	Printed on box and on each test kit
OraQuick® ADVANCE HIV	Printed on box and on each test kit
OraQuick® HCV	Printed on box and on each test kit

Test Kit Disposal – Expired or Compromised
When a test kit exceeds the expiration date printed on the box or foil pouch DO NOT use the test kit to conduct client testing. A test kit is also compromised if:

- the developer vial is empty
- the foil pouch is pierced
- a shake of the test kit pouch produces no rattle sound
- the test device has been removed from the foil pouch and dropped
- the test device has been compromised by being exposed to extreme temperatures above/below manufacturer's specifications and recommendations

You may elect to retain a limited number of test devices to be used for training and education exercises. Mark 'TRAINING' or 'DEMO" on the outside of each test kit pouch and store in a different location from the unexpired test kits. When discarding test kits, open the foil pouch and place the test device in one garbage receptacle and the developer vial in a second receptacle.

NOTE: Expired or compromised kits may provide an incorrect test result.

5. Lab Supply List

The following supplies are listed to help ensure an efficient lab. Rapid testing requires unique supplies, some of which are:

- Test kits – rapid HIV/HCV
- Controls – rapid HIV/HCV
- Weight boats and pipettes
- Test stands
- Collection loops
- Rapid HIV/HCV subject information pamphlets
- Rapid HIV/HCV product insert
- Day of test log
- Temperature logs – test kits and controls
- OraQuick Advance supplemental preliminary-positive test device
- Finger stick and lab supplies (alcohol swabs, cotton balls, sharps container, finger bandages, exam gloves, absorbent surface pads, bleach solution, biohazard bags, etc.)
- Scientific thermometer
- Timer or clock
- 10% bleach solution
- Portable cooler and frozen packs (outreach)

For a complete lab set-up checklist please visit:
http://health.utah.gov/cdc/hivprevention/hiv_prev_provider_resources.htm

6. Selecting the Lab Site

Whether at a main test site or when conducting outreach testing, consider the following when selecting the best lab location:

- A dedicated area exclusively to run and monitor tests
- Sufficient level counter space to run and monitor tests
- Consistent room temperature
- Sufficient lighting to read the test window
- Sufficient area to store supplies
- Ability to lock room or limit access
- Ability to maintain confidentiality of clients
- Ability to maintain client files in a secure manner

6.1 Lab Temperature Range

Lab temperature requirements are specific to each type of rapid test. The temperature of the specimen collection area must fall within a defined range. Whenever the temperature falls outside the minimum or maximum operating temperature, NO new clients may be tested until the temperature is once again within range. Any tests running are allowed to run their time and be interpreted as usual.

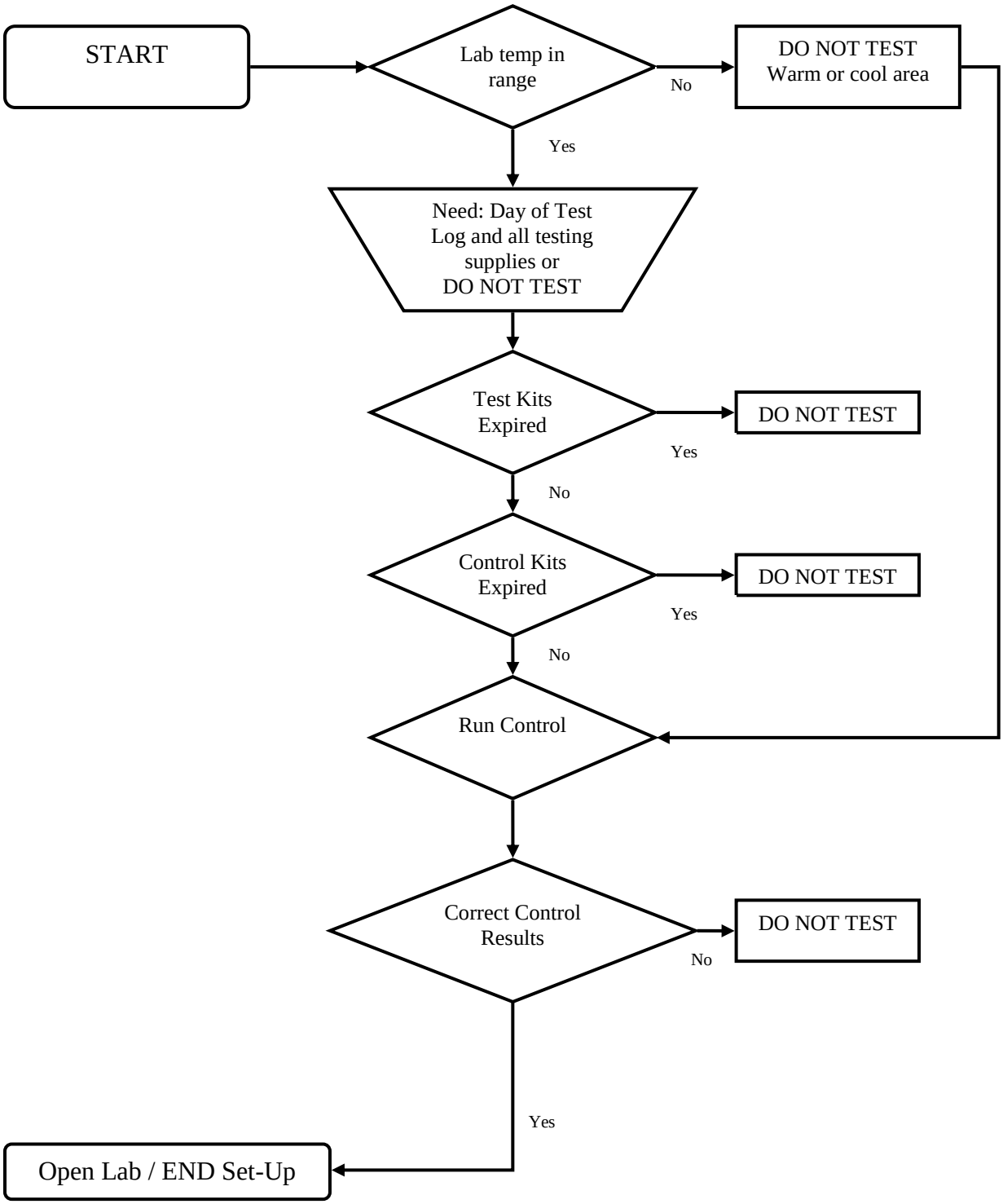
Once the temperature is within range, run one negative external control and one external positive control to verify that test kits are operating in accordance with the manufacturer's design. Only after controls have run their full time and have been interpreted correctly (one negative and one positive) can client testing commence or resume.

Test Kit Type	Lab Temperature Range
Clearview® COMPLETE	64° - 86°F or 18° - 30°C
OraQuick® ADVANCE HIV	59° - 99°F or 15° - 37°C
OraQuick® HCV	59° - 99°F or 15° - 37°C

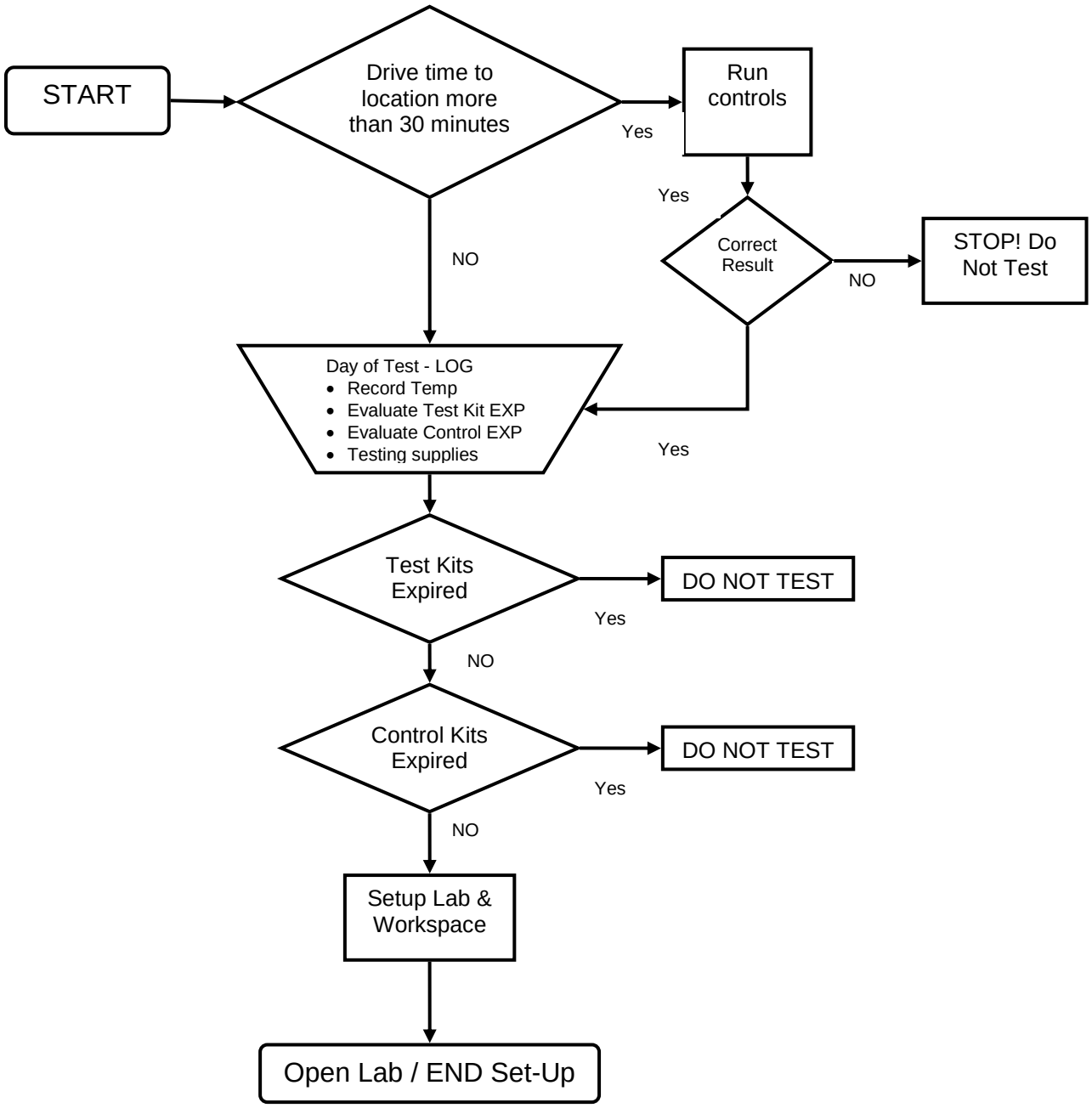
Average temperature range for all labs	**64° - 86°F or 18° - 30°C**

7. Lab Set-up Flow Charts

7.1 Lab Set-up Flowchart (Clinic or On-Site Testing)



7.2 Lab Set-up Flowchart (Outreach Settings)



8. HIV and HCV External Control Reagents

HIV and HCV controls kits are different and specific to each infection. The exchange of external controls and test devices within or between manufacturers is not permitted. The test result will not be accurate and render any test result invalid.

8.1 HIV Controls

The HIV control kit includes one vial of negative fluid, one vial of HIV-1 positive fluid and one vial of HIV-2 positive fluid (positive fluids are deactivated and do not pose a contamination risk). HIV-2 will not be used when routinely running controls. Review section 1.2 on testing for HIV-2 in the United States for additional guidance.

8.2 HCV Controls

The HCV control kit includes one vial of negative fluid and one vial of HCV positive fluid (positive fluids are deactivated and do not pose a contamination risk).

<table>
<tr><th colspan="2">When to Run Controls for HIV and HCV</th></tr>
<tr><td><u>ALL testing locations:</u>
Each new lab operator
First time lab set-up at main facility
Each new lot of test kits
Each new shipment of test kits
Temperature of specimen collection area and lab exceeds the temperature window (specific to each test)
Temperature of the test storage area exceeds the temperature window (specific to each test)
Whenever the number of preliminary positive result exceeds 1% of the sites historical incident rate
Best practice is to maintain two sets of unexpired controls at the testing location under cold storage.</td><td><u>OUTREACH testing locations:</u>
Each new lab operator
When test kits are transported to an outreach location and the travel time is more than 30 minutes
Each new lot of test kits
Each new shipment of test kits
Temperature of specimen collection area and lab exceeds the temperature window (specific to each test)
Temperature of the test storage area exceeds the temperature window (specific for each test)
Whenever the number of preliminary positive result exceeds 1% of the sites historical incident rate
Best practice is to maintain two sets of unexpired controls at the testing location and stored in a portable cooler where the temperature range can be maintained and verified.</td></tr>
</table>

8.3 Running External Controls

Use a methodical approach when running controls, such as introducing the negative reagent into one test device/developer vial before introducing the positive reagent in the second test device/developer vial. This will minimize errors with duplicate reagents. For additional support, refer to the customer letter/product insert/package insert included in the box of controls for operating procedures.

The desired result is one HIV-1 negative and one HIV-1 positive test rest. This indicates that the test device is operating correctly and client testing may begin. Client testing should not take place before the control run is finished and desired results interpreted.

If any other result is present, repeat the control run with two new test kits. If the second control run result differs from one negative and one positive, contact the CDPP for guidance and technical assistance (refer to page 2 for CDPP contact details).

For more information on running controls:

For Clearview COMPLETE HIV 1/2 visit:
http://www.alere.com/us/en/product-details/clearview-complete-hiv-1-2.html

For OraQuick ADVANCE HIV 1/2 visit:
http://www.orasure.com/products-infectious/products-infectious-oraquick.asp

For OraQuick Rapid HCV Antibody visit:
http://www.orasure.com/products-infectious/products-infectious-oraquick-hcv.asp

9. General Testing

9.1 Testing Capacity

Direct observation and staff interviews have determined that one lab technician can efficiently administer and monitor up to five tests in one 60-minute period. Whenever more than five tests are administered in one 60-minute period, it is strongly suggested that one person perform specimen collection and another person monitor tests and lab paperwork. Only certified lab technicians are qualified to interpret test results, and/or sign-off as a conferring opinion.

For rapid HIV testing: At least one staff member who is certified to give preliminary positive results must be present at all times while rapid HIV testing is being conducted.

For rapid HCV testing: At least one HCV prevention counselor, who has been certified to give reactive results and provide appropriate referrals, must be present at all times while rapid HCV testing is being conducted.

9.2 High Volume Testing

High volume testing can require increased capacity and resources. To ensure quality testing and accurate results, consideration can be given to partnering with trained staff at other agencies. Please contact the CDPP for more information.

10. Conducting HIV and HCV Rapid Tests

10.1 Clearview® COMPLETE – whole blood collection

Brief Instructions:

- Clean finger with alcohol pad
- Let air dry or dry with sterile cotton/gauze (do not blow on the finger)
- Perform the fingerstick
- Wipe away the first drop of blood with a cotton ball/sterile gauze
- Avoid squeezing the finger to accelerate bleeding
- Touch the sampler tip to the blood drop until the sampler tip is full
- Run test
- Make sure the test device is pushed in all the way into the developer solution

When using venous blood, remove the cap from the vial and collect a drop from the inside of the blood tube cap.

For more information on administering Clearview® COMPLETE HIV 1/2 tests visit: http://www.alere.com/us/en/support/education.html or reference the package insert.

10.2 OraQuick® ADVANCE HIV & HCV – whole blood collection

Brief Instructions:

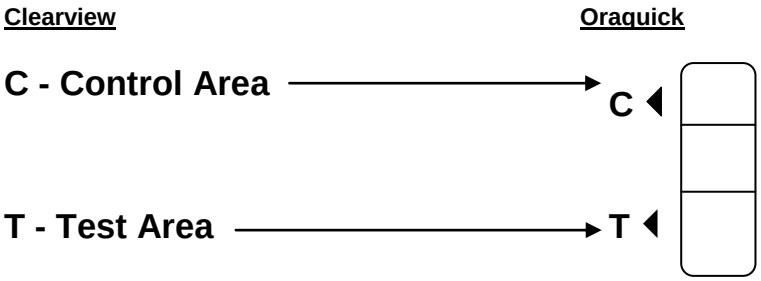
- Wipe finger with alcohol pad
- Let air dry or dry with sterile cotton/gauze (do not blow on the finger)
- Perform the fingerstick
- Wipe away the first drop of blood with a cotton ball/sterile gauze
- Avoid squeezing the finger to accelerate bleeding
- Collect blood drop with the OraQuick loop making sure the blood completely fills the loop from side to side
- Mix with the developer solution and run test

For more information on administering OraQuick® ADVANCE HIV1/2 Rapid Antibody and OraQuick® HCV Rapid Antibody tests visit: http://www.orasure.com/products-infectious/products-infectious-oraquick-hcv.asp or reference the package insert.

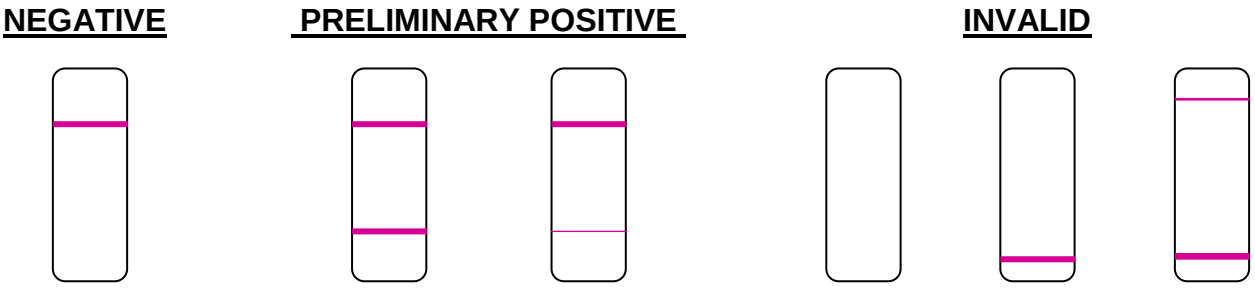
11. Interpreting Test Results

The result window of all three test devices is similar, one line is a negative test result, and two lines is a preliminary positive test result. Any other reading is an invalid result.

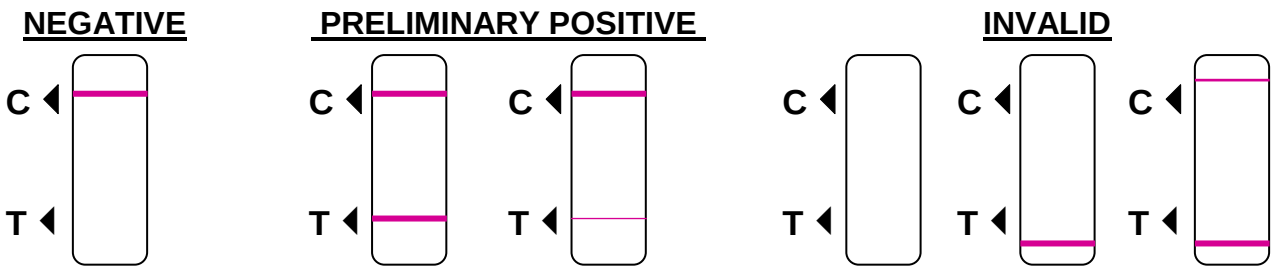
Clearview COMPLETE ® has identified the top 1/3 of the read window as the "control" area and the bottom 1/3 of the read window as the "test" area. OraQuick® ADVANCE HIV and HCV has identified the "C" triangle as the control area of the read window and the "T" triangle as the test area of the read window.



Clearview® COMPLETE HIV 1/2



OraQuick® ADVANCE HIV 1/2 & HCV



11.1 Negative or Non Reactive Result

One pink/purple line appears; one line next to the "C" triangle or top 1/3 of the read window and no line next to the "T" triangle or bottom 1/3 of the read window indicates a negative result. A negative result means no antibodies were detected in the specimen.

11.2 Preliminary Positive or Reactive Result

Two pink/purple lines appear; one in the "C" triangle or top 1/3 of the read window and one in the "T" triangle or bottom 1/3 of the read window indicating a preliminary positive test result. Intensities of the two lines may vary. A preliminary positive result means antibodies were detected in the specimen. Preliminary positive results need to be validated by two trained staff members.

11.3 Invalid Result

An invalid result occurs when:

- no pink/purple lines appear in the read window
- no pink/purple line appears next to the "C" triangle or in the top 1/3 of the read window
- lines appear around the side of the "C" triangle and "T" triangle or top and bottom 1/3 of the read window

DO NOT interpret an invalid test result as negative or preliminary positive; An invalid test occurs when there was either a problem running the test, or a problem related to the sample, the device, or the testing procedure. Record the lot number and report to CDPP and retest the client with a new test device.

12. Preliminary Positive Results & Confirmatory Testing

12.1 HIV

All preliminary positive test results should be 'confirmed' to determine the client's HIV status. Once a second test is interpreted as positive/reactive , the counselor can initiate discussions about general health care and partner services before the client is actively referred to care.

For rapid HIV testing: All preliminary HIV positive results must be confirmed by either a second rapid test (rapid-rapid test practice), or by a conventional blood draw test. When offering rapid-rapid testing, the second rapid test must be from a different manufacturer. The CDPP recommends Clearview COMPLETE HIV1/2 as the first HIV rapid test and OraQuick ADVANCE Rapid HIV 1/2 for the second. Clients can also be referred to a local health department for confirmatory testing by blood drawing. Two rapid preliminary positive results must be achieved before referring the client to care.

Test Sequence	Result	Next Step
Rapid HIV (Test 1)	(N) HIV Negative	**STOP**
Rapid HIV (Test 1)	(PP) HIV Preliminary Positive	a) Administer 2nd rapid test **OR** b) Refer client to local health department for confirmatory testing The local health department will follow up with the client and conduct Partner Services
Rapid HIV (Test 2)	(N) HIV Negative	a) Retest client (4 weeks after test 1) **OR** b) Refer client to local health department The local health department will follow up with the client and facilitate partner services
	(PP) HIV Preliminary Positive	Refer client to: a) medical care b) Partners Services, and c) HIV prevention serivces

12.2 HCV

For rapid HCV testing: The HCV rapid test is a screening test which detects HCV antibodies, therefore it cannot determine if someone is actively infected with HCV. In order to determine if someone is actively infected with HCV, additional testing must be done. This testing may include HCV RNA testing by PCR. Refer to the CDPP for more information on confirmatory HCV testing.

Test Sequence	Result	Next Step
Rapid HCV (Test 1)	(N) HCV Negative	**STOP**
	(PP) HCV Preliminary Positive	Refer to local health department or medical provider for confirmatory testing

13. Data Collection and Reporting

Required Day of Test Logs and Temperature Logs (tests kits and external controls) are to be maintained by the agency for 18 months and made available to CDPP staff for audit as requested.

14. Quality Assurance

Quality assurance (QA) is the foundation of a successful testing program. QA standards ensure the accuracy of the test and results, as well as the quality of service that agencies deliver.

Although waived rapid tests are easy to use, mistakes can occur at any point during the testing process. To reduce mistakes the testing site must have a QA program in place before waived rapid antibody testing can be offered. The basic elements of a QA program for rapid testing include:

- Organization of the QA program
- Personnel who will conduct testing
- Process control
    - before, during and after testing
- External assessment
- Documentation and record-keeping
- QA evaluation and troubleshooting

More information on how to establish a QA program can be found at:
http://www.cdc.gov/hiv/pdf/testing_QA_Guidlines.pdf

For internal assessment, agencies should review the rapid test documents each day after testing ends or at the conclusion of each week. A regular review process allows timely feedback to rapid testing staff and provides coaching when needed. Test kit storage logs, control kit storage logs and day of test logs should be retained for 18 months.

CDPP staff will review rapid testing documents periodically and provide feedback to the agency. Technical assistance and training will be provided when appropriate.

For examples of the day of test log, test kit storage log and control kit storage log, visit: http://health.utah.gov/cdc/hivprevention/hiv_prev_provider_resources.htm or refer to Appendix A of this document.

Appendix A – Required Logs (Examples)

1. Day of Test Log

Test Site _____ Date _____

Site Type [ ] Main Site [ ] Outreach Lab Technician _____

Test Kit LOT# CC_____ HCV_____ Test Kit EXP Date CC___/___ HCV___/___

OQA_____ _____ OQA___/___

Client Log

	Test Type	Client ID	Lab Temperature Average 18° - 30°C or 64°- 86°F	Start Time	Read Time	HCV read 20-40 min. HIV read 15-20 min. HIV conf read 20-40 min. **YES** - test next CLT **NO** - retest this CLT	Result (✓ one) N	PP	I	Done by
C	HIV CC	Control HIV (-)				[ ]Yes [ ]No				
C	HIV CC	Control HIV (+)				[ ]Yes [ ]No				
C	HCV	Control HCV (-)				[ ]Yes [ ]No				
C	HCV	Control HCV (+)				[ ]Yes [ ]No				
C	HIV OQA	Control HIV (-)				[ ]Yes [ ]No				
C	HIV OQA	Control HIV (+)				[ ]Yes [ ]No				
1	[ ]HIV [ ]HCV					[ ]Yes [ ]No				
2	[ ]HIV [ ]HCV					[ ]Yes [ ]No				
3	[ ]HIV [ ]HCV					[ ]Yes [ ]No				
4	[ ]HIV [ ]HCV					[ ]Yes [ ]No				
5	[ ]HIV [ ]HCV					[ ]Yes [ ]No				
6	[ ]HIV [ ]HCV					[ ]Yes [ ]No				
7	[ ]HIV [ ]HCV					[ ]Yes [ ]No				
8	[ ]HIV [ ]HCV					[ ]Yes [ ]No				
9	[ ]HIV [ ]HCV					[ ]Yes [ ]No				
10	[ ]HIV [ ]HCV					[ ]Yes [ ]No				

RESULT = (N) Negative, (PP) Preliminary Positive, (I) Invalid

TOTAL - **N** ☐

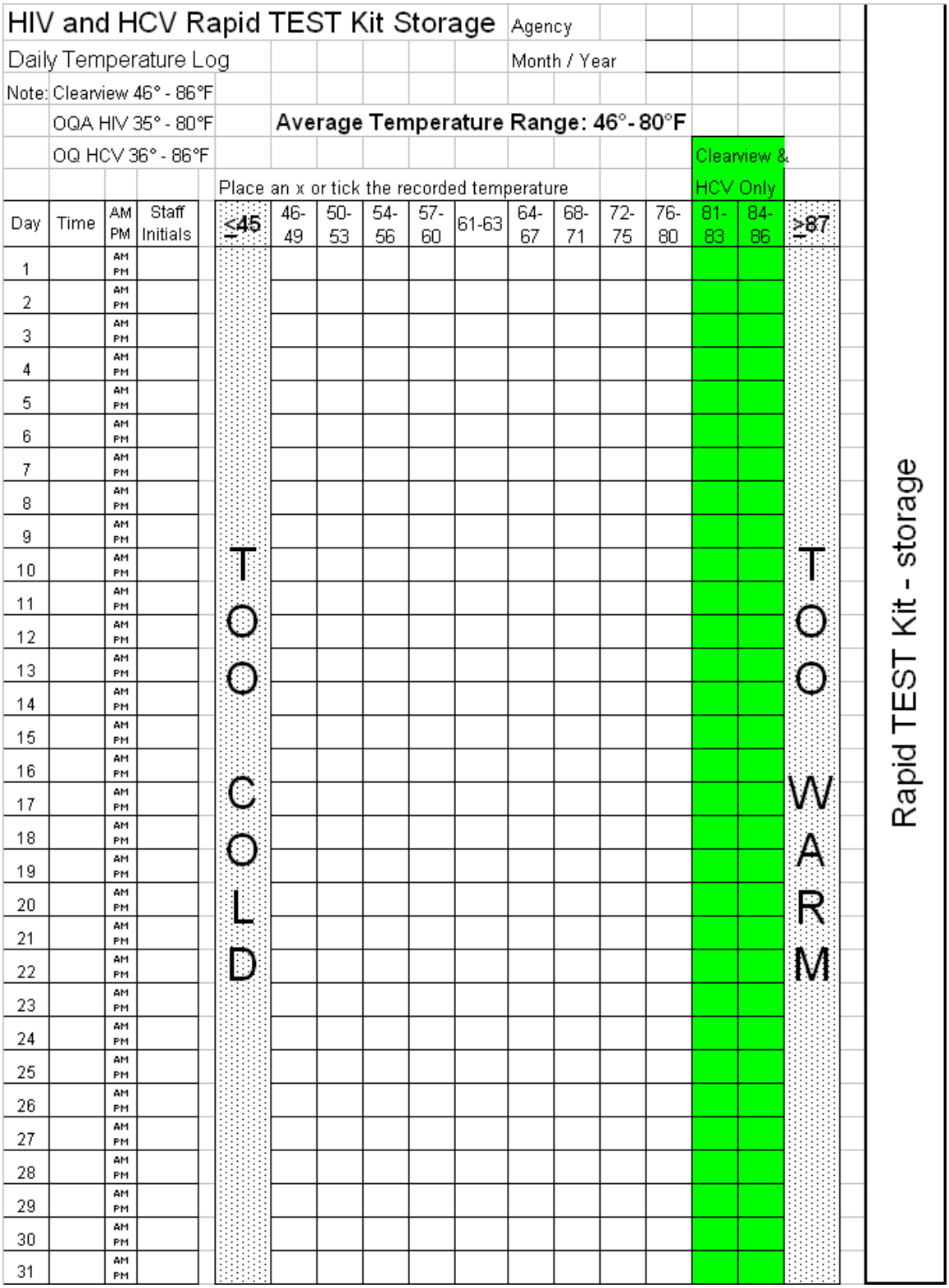
TOTAL - **PP** ☐

TOTAL - **I** ☐

Notes: _____

HIV and HCV Day of Test LOG

2. Test Kit Temperature Storage Log (Fahrenheit)



HIV and HCV Rapid TEST Kit Storage — Agency

Daily Temperature Log — Month / Year

Note: Clearview 46° - 86°F

OQA HIV 35° - 80°F

OQ HCV 36° - 86°F

Average Temperature Range: 46°-80°F

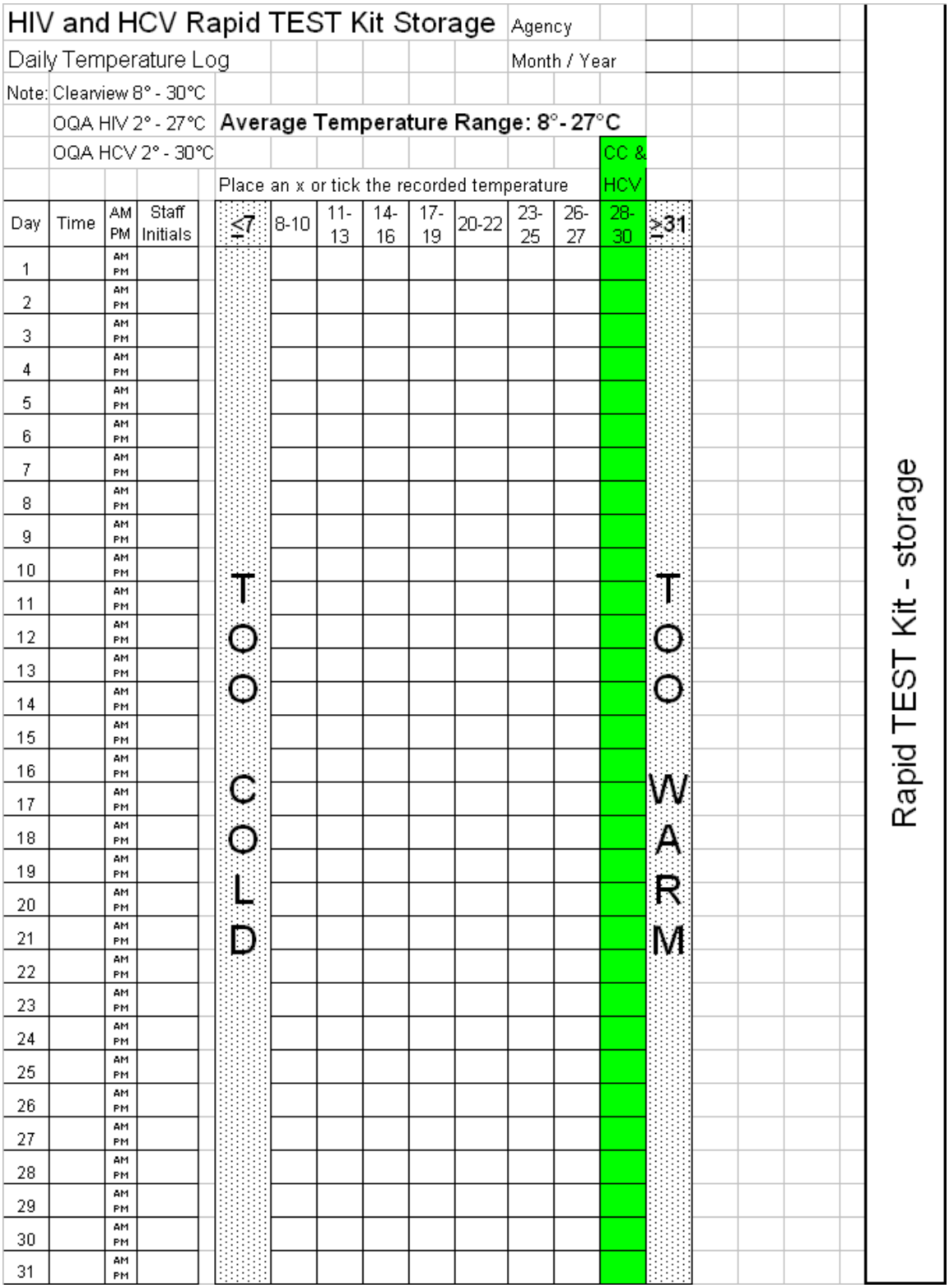
Clearview & HCV Only

Place an x or tick the recorded temperature

Day	Time	AM PM	Staff Initials	≤45	46-49	50-53	54-56	57-60	61-63	64-67	68-71	72-75	76-80	81-83	84-86	≥87
1		AM PM		TOO COLD												TOO WARM
2		AM PM														
3		AM PM														
4		AM PM														
5		AM PM														
6		AM PM														
7		AM PM														
8		AM PM														
9		AM PM														
10		AM PM														
11		AM PM														
12		AM PM														
13		AM PM														
14		AM PM														
15		AM PM														
16		AM PM														
17		AM PM														
18		AM PM														
19		AM PM														
20		AM PM														
21		AM PM														
22		AM PM														
23		AM PM														
24		AM PM														
25		AM PM														
26		AM PM														
27		AM PM														
28		AM PM														
29		AM PM														
30		AM PM														
31		AM PM														

Rapid TEST Kit - storage

2a. Test Kit Temperature Storage Log (Celsius)



HIV and HCV Rapid TEST Kit Storage — Agency

Daily Temperature Log — Month / Year

Note: Clearview 8° - 30°C

OQA HIV 2° - 27°C — **Average Temperature Range: 8°- 27°C**

OQA HCV 2° - 30°C

Place an x or tick the recorded temperature

Day	Time	AM PM	Staff Initials	≤7	8-10	11-13	14-16	17-19	20-22	23-25	26-27	28-30 CC & HCV	≥31
1		AM PM		TOO COLD									TOO WARM
2		AM PM											
3		AM PM											
4		AM PM											
5		AM PM											
6		AM PM											
7		AM PM											
8		AM PM											
9		AM PM											
10		AM PM											
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12		AM PM											
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25		AM PM											
26		AM PM											
27		AM PM											
28		AM PM											
29		AM PM											
30		AM PM											
31		AM PM											

Rapid TEST Kit - storage

3. Control Kit Temperature Storage Log (Fahrenheit)

HIV and HCV Rapid CONTROL Kit Storage Agency _____

Daily Temperature Log Month / Year _____

Refrigerator temperature range 35°- 46°F

Place an 'x' or ✓ on the recorded temperature

Day	Time	AM PM	Staff Initials	≤32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	≥49
1		AM PM																			
2		AM PM																			
3		AM PM																			
4		AM PM																			
5		AM PM																			
6		AM PM																			
7		AM PM																			
8		AM PM																			
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28		AM PM																			
29		AM PM																			
30		AM PM																			
31		AM PM																			

TOO COLD

TOO WARM

Rapid CONTROL Kit - storage

3a. Control Kit Temperature Storage Log (Celsius)

HIV and HCV Rapid CONTROL Kit Storage Agency _____

Daily Temperature Log Month / Year _____

Refrigerator temperature range 2º- 8ºC

Place an 'x' or ✓ on the recorded temperature

Day	Time	AM PM	Staff Initials	-1	0	1	2	3	4	5	6	7	8	9	10	≥11
1		AM PM														
2		AM PM														
3		AM PM														
4		AM PM														
5		AM PM														
6		AM PM														
7		AM PM														
8		AM PM														
9		AM PM														
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27		AM PM														
28		AM PM														
29		AM PM														
30		AM PM														
31		AM PM														

TOO COLD

TOO WARM

Rapid CONTROL Kit - storage